K00 2224

DEC - 4 2000

510(k) Summary

1.0 Date Prepared

October 23, 2000

2.0 Submitter (Contact)

Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name: XPS 3000 System
Common Name(s): Electrical surgical shavers, electrical microresectors, mastoid drills, microdrill, ENT drills, handpieces and cutting blades, rasps and burs
Classification Name(s): Drill, Surgical, ENT (Electric or pneumatic) including handpiece

4.0 Device Classification

Classification Name: Drill, surgical, ENT (electric or pneumatic) including handpiece
Procode: 77ERL Class II 21 CFR § 874.4250

5.0 Device Description

The XPS 3000 system consists of a power control console, footswitches, connection cables, and assorted handpieces to drive various burs, blades, drills, rasps, and cannulae.

6.0 Indications for Use

The XPS 3000 is intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery.

Otology indications include mastoidectomy and mastoidotomy.

Sinus indications include septoplasty, removal of septal spurs, polypectomy, antrostomy, ethmoidectomy/sphenoethmoidectomy, frontal sinus trephination and irrigation, frontal sinus drill out, endoscopic DCR, and trans-spehniodal procedures.

Nasopharyngeal/laryngeal indications include adenoidectomy, tracheal procedures, laryngeal polypectomy, laryngeal lesion debulking, and tonsillectomy.

Head and neck (ENT) indications include soft tissue shaving, rhinoplasty (narrowing of the bony vault and revision of the bony pyramid), removal and shaping of bone during rhinoplasty procedures, removal of adipose tissue (lipo debridement) in the maxillary and mandibular regions of the face, removal of acoustic neuroma, and incision and removal of soft tissue during plastic, reconstructive, and/or aesthetic surgery.

The XPS 3000 system using the PowerSculpt handpiece and reciprocating cutting blades / rasps is indicated to cut hard and soft tissue or bone in otorhinolaryngology and head and neck surgery.

An integral pump is provided for irrigation, and a second integral pump may be provided for handpiece cooling.

7.0 Substantial Equivalence

The proposed XPS 3000 system is substantially equivalent in operating principle, technology, overall design, function, materials, and intended use to the XPS Straight Shot / 2000 System (K963246), Linvatec E9000 (K990524), and the Smith & Nephew Turbo 7000 System (K992994).

Characteristic	Proposed XPS 3000 system	Linvatec E9000	Smith & Nephew Turbo 7000 System	XPS Straight Shot / 2000 System
Clearance	–	K990524	K992994	K963246
Intended use / Indications for use	Cutting soft tissue and bone (See Appendix X for specific intended use)	Cutting soft tissue and bone (See Appendix N for specific intended use)	Cutting soft tissue and bone (See Appendix O for specific intended use)	Cutting soft tissue and bone (See Appendix U for specific intended use)
Bone Drill	80,000 RPM	80,000 RPM	Unknown	52,000 RPM
Bone Drill cooling method	Sterile liquid	Sterile liquid	Unknown	Convection
Microresector FWD / REV Speed	Default: 6,000 RPM Max: 15,000 RPM	Default: 5,000 RPM Max: 10,000 RPM	Default: Unknown Max: 7,000 RPM	Default: 6,000 RPM Max: 6,000 RPM
Microresector (Oscillation speed)	Default: 3,000 RPM Max: 5,000 RPM	Default: 3,000 RPM Max: 5,000 RPM	Default: Unknown Max: 3,000 RPM	Default: 3,000 RPM Max: 3,000 RPM
Steam autoclavable Handpiece	Yes	Yes	Yes	Yes
Blade Sizes (O.D.)	2.9mm – 6mm	Unknown	3.0mm – 4.0mm	3.5mm – 6mm
Direct patient contacting material (blades / burs)	Stainless steel and medical polymer	Stainless steel and medical polymer	Unknown	Stainless steel and medical polymer
Blades / burs biocompatible	Yes	Yes	Yes	Yes
Perastaltic pumps	2 pumps (1 for irrigation and 1 optional pump for handpiece cooling)	1 pump (used for irrigation and/or handpiece cooling)	1 pump (used for irrigation)	1 optional pump (used for irrigation)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Mr. Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
6743 Southpoint Dr. N.
Jacksonsville, FL 32216

Re: K002224
Trade Name: XPS 3000 System
Regulatory Class: II
Product Code: ERL 77
Dated: October 23, 2000
Received: October 25, 2000

Dear Mr. Sargent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002224
Device Name: XPS 3000 System
Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002224

Prescription Use ✓ Or Over-the-Counter Use _____
(Per 21 CFR 801.109)